

## SECTION 7

## SUMMARY OF SAFETY AND EFFECTIVENESS

**510(k) Summary of Safety and Effectiveness**

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

NEW DEVICE NAME: Endoscopic Applicator

PREDICATE DEVICE NAME: Endoscopic Applicator

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**510(k) SUMMARY**

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**Device Description**

The Endoscopic Applicator device is a sterile single use, disposable device intended for use in delivering hemostatic agents to bleeding surgical sites through a 5mm trocar or larger. The Endoscopic Applicator consists of two components; (1) a minimally reflective stainless steel cannula and (2) a plastic stylet (obturator). The Endoscopic Applicator is designed with a luer connector, for connection to a syringe containing the hemostatic agent.

The packaging used for the Endoscopic Applicator is a pouch that consists of a see-through laminated film and TYVEK. Alternatively, a second pouch may be used. Either package configuration is placed within a paperboard carton.

**Intended Use**

The Endoscopic Applicator is intended for use in delivering hemostatic agents to bleeding surgical sites through a 5mm trocar or larger.

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SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

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**Indications Statement**

The Endoscopic Applicator is indicated for use in delivering hemostatic agents to bleeding surgical sites through a 5mm trocar or larger.

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**Technological Characteristics**

The technological characteristics of the new device are the same as the predicate device in that they both consist of a cannula and a stylet that is used to deliver hemostatic agents to bleeding sites through a 5mm trocar or larger. The new device is provided sterile, for single patient use and is disposable.

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**Performance Data**

The Endoscopic Applicator( New Device) and the predicate device have the same intended use. The new device is substantially equivalent to the predicate device in intended use, technological characteristics, design, components and materials, therefore, performance testing was considered unnecessary. Clinical data was deemed unnecessary to demonstrate equivalence of the new device to the predicate device for its intended purpose.

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**Conclusions**

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.

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**Contact**

Peter M. Cecchini  
Fellow, Regulatory Affairs  
ETHICON, Inc.  
Rt. #22, West  
Somerville, NJ 08876-0151

**Date**

June 27, 2005

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 9 - 2005

Mr. Peter M. Cecchini  
Fellow, Regulatory Affairs  
ETHICON, Inc.  
Route 22 West  
Somerville, New Jersey 08876

Re: K051732

Trade/Device Name: Endoscopic Applicator  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: GCJ  
Dated: June 27, 2005  
Received: June 28, 2005

Dear Mr. Cecchini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

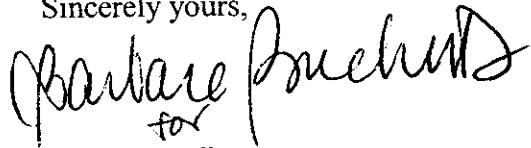
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Mark N. Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K051732

**INDICATION FOR USE**

510(k) Number (if known):

Device Name: Endoscopic Applicator

Indications for Use: The Endoscopic Applicator is intended for use in delivering hemostatic agents to bleeding surgical sites through a 5mm trocar or larger.

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ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X \_\_\_\_\_

OR

Over-The Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-9G)

Denbare Bruehns for MWD

(Division Sign-Off)

Division of General Restorative  
and Neuromodulatory Devices

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510(k) Number K051732